What is claimed is:

1. A pharmaceutical liposomal formulation for photodynamic therapy comprising a liposomal bilayer which consists substantially of phospholipids, and a therapeutically effective amount of a non-polar photosensitizer.

2. The liposomal formulation according to claim 1, wherein said phospholipids are selected from the group consisting of dipalmitoyl phosphatidyl choline, dipalmitoyl phosphatidyl glycerol, poly (ethylene glycol)-linked phospholipids and combinations of these three materials.

3. The liposomal formulation according to claim 1 wherein said photosensitizer is a porphyrin macrocycle photosensitizer.

4. The liposomal formulation according to claim 1 wherein said porphyrin macrocycle photosensitizer is selected from the group consisting of deuteroporphyrin, etioporphyrin, protoporphyrin, hematoporphyrin, pheophorbide and their di- and tetra-hydroporphyrin derivatives.

5. The liposomal formulation according to claim 1, which has been freeze dried, further comprising one or more monosaccharides or polyalcohols, and wherein the freeze dried formulation, upon addition of a suitable aqueous vehicle, forms liposomes containing a therapeutically effective amount of the non-polar photosensitizer within the liposomal bilayer.

6. The liposomal formulation according to claim 5 wherein said monosaccharide is selected from the group consisting of glucose and fructose.

7. The liposomal formulation according to claim 5 wherein said polyalcohol is selected from the group consisting of inositol and mannitol.

8. The liposomal formulation according to claim 5 wherein the concentration ratio of monosaccharide to phospholipid is between 1:2 and 1:12.

9. The liposomal formulation according to claim 5 wherein the concentration ratio of polyalcohol to phospholipid is between 1:2 and 1:12.

10. The liposomal formulation according to claim 5, reconstituted with an aqueous fluid for pharmaceutical administration.

11. The liposomal formulation according to claim 1 wherein the therapeutically effective concentration of the photosensitizer is from 0.0001 to 0.15 percent w/v.

12. The liposomal formulation according to claim 5 wherein the therapeutically effective concentration of the photosensitizer is from 0.0001 to 0.15 percent w/v.

13. The liposomal formulation according to claim 1 further comprising a component selected from the group consisting of butylated hydroxytoluene, ascorbic palmitate, and combinations of these two.

14. The liposomal formulation according to claim 5 further comprising a component selected from the group consisting of butylated hydroxytoluene, ascorbic palmitate, and combinations of these two.

15. The liposomal formulation according to claim 1 wherein the formulation further comprises at least one additional pharmaceutically active substance, especially polar, suitable to have some beneficial effect in a preselected therapy.

16. The liposomal formulation according to claim 5 wherein the formulation further comprises at least one additional pharmaceutically active substance, especially polar, suitable to have some beneficial effect in a preselected therapy.

Abstract of the Invention

A pharmaceutical liposomal formulation for photodynamic therapy comprising a non-polar porphyrin photosensitizer and one or more phospholipids, which are stable in storage without requiring freeze-drying is described. The liposomal formulation provides therapeutically effective amounts of the photosensitizer for intravenous administration. The phospholipids may be modified by pegylation, i.e. they contain poly ethylene glycol as an integral part of the phospholipids. The formed liposomes contain the non-polar photosensitizer within the membrane and are useful for the combined targeting of a non-polar photosensitizer and a second polar substance. When a formulation includes the presence of monosaccharides or polyalcohols, it can be efficiently freeze-dried preserving the size of the liposomal vehicles and the content of a therapeutically effective amount of the photosensitizing agent. The invention also relates to the liposome composition formed upon reconstitution with an aqueous vehicle. The freeze-dried formulation upon reconstitution with a suitable aqueous vehicle forms liposomes that are also useful for intravenous administration.